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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,344	07/08/2003	Linda D. Artman	085747-0245	7848

22428 7590 02/07/2005

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EXAMINER

SHARAREH, SHAHNAMEH J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,344

Applicant(s)

ARTMAN ET AL.

Examiner

Shahnam Sharareh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 and 39 is/are allowed.
- 6) ☒ Claim(s) 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on October 19, 2004 has been entered. Claims 37-39 are pending.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendment. The terminal disclaimer filed on October 19, 2004 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 6,589,994 has been reviewed and is accepted. The terminal disclaimer has been recorded. Accordingly, the obviousness-type double patenting rejection has been withdrawn.

Applicant's amendment has overcome the rejections made under the statutory double patenting and under the 35 USC § 102 (e). Accordingly, said rejections are withdrawn.

Allowable Subject Matter

Claims 37 and 39 are allowed, because the prior art does not teach or reasonably disclose methods of treating convulsions and headaches in patients in need thereof by administering effective amounts of isovaleramide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balandrin et al US Patent 5,506,268.

Claim 38 is directed to a method treating spasticity in a patient in need thereof comprising administering an effective amount of isovaleramide. The scope of the term "spasticity" is described in pages 6-8 of the instant specification. Accordingly, "spasticity" is viewed to encompass any heightened tone of skeletal muscles or increase tonic stretch reflexes (muscle tone) which can result from hyperflexability of the muscles and can be manifested by exaggerated tendon jerks. Therefore, the limitation of "treating spasticity" is viewed to encompass any alleviation that lessens one or more symptoms of spasticity, including decreasing muscle tone. (see instant specification at pages 6-8).

Balandrin teaches Isovaleramide as an anxiolytic agent in patients in need thereof. Even though, Balandrin does not specifically teach methods of treating spasticity, Balandrin provides various specific teachings that meet the limitations of the instantly claimed methods of treating spasticity.

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Balandrin first states that isovaleramide is prepared from extracts of *valeriana officinalis*, which has historically been used as sedative and antispasmodics. (see col 1, lines 55-58). Balandrin then specifically states that the anxiolytic effects of isovaleramide leads to a decrease in general locomotor and spontaneous locomotor activity. (col 5, lines 60-67; col 7, lines 6-10; col 9, lines 64-67; col 10, lines 23-28). Such decrease in locomotor activity is viewed to fall within the scope of the instant limitation "treating spasticity." Balandrin administered isovaleramide as hypnotic to patients in a hypertonic state such as hyperexcitable children, premenstrual patients, substance abuse patients. Therefore, the population described in Balandrin falls within the scope of the population describe in the instant claims. The doses employed for Balandrin to trigger a decrease in locomotor activity also falls within the range of instant claims. Thus, all limitations of claim 38 are describe by Balandrin.

Accordingly, Even though, Balandrin does not explicitly teach methods of treating spasticity, it would have been obvious to one of ordinary skill in the art at the time of invention to employ isovaleramide as described by Balandrin as an antispasmodic agent, because not only the parent extract of such compound provides antispasmodic properties, but also Balandrin explicitly provides evidence of decrease in locomotor activity. Thus, one of ordinary skill in the art would have had a reasonable expectation of success in treating conditions associated with spasticity by administering isovaleramide at doses taught by Balandrin.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER